INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF DEFENSE AND THE NATIONAL CANCER INSTITUTE FOR PARTNERSHIP IN CLINICAL TRIALS FOR CANCER PREVENTION AND TREATMENT

INTRODUCTION:

This interagency agreement is being entered into pursuant to Title 10, United States Code, section 1079(a)(13).

The National Cancer Institute (NCI), of the Department of Health and Human Services, sponsors and actively coordinates an extensive clinical trials program for the evaluation of prevention, early detection, treatment, and supportive care for various types of cancer. The NCI's program includes sponsorship of studies in single institutions, as well as large, multi-center, randomized trials in cooperative networks. The trials encompass studies of cancers occurring in virtually all anatomical sites and in all stages of development. The NCI clinical trials program has been the means by which the oncology community has developed most of the formal clinical evidence for the efficacy of the various prevention, early detection, and management approaches in clinical cancer.

The Department of Defense (DoD) provides and maintains readiness of medical services and support to the Armed Forces during military operations, and to provide health services and support to members of the armed forces, their family members, and to others entitled to DoD medical care. These medical services are provided to approximately 9.2 million beneficiaries through the direct care system, comprised of military treatment facilities (MTFs), and through care purchased from civilian providers whose services are reimbursed by TRICARE. The TRICARE program integrates the full range of health care in the direct care system with care in the civilian sector. It offers beneficiaries health care choices through enrollment in a HMO-like option called TRICARE Prime, a voluntary PPO-like option called TRICARE Extra, or through an indemnity-like option called TRICARE Standard.

Beginning in 1996, the DoD conducted a demonstration project which provided patients with an opportunity to participate in Phase II and Phase III NCI sponsored cancer treatment clinical trials either in the direct care system or through civilian providers whose services were reimbursed through TRICARE. In 1999, they expanded this partnership with NCI to allow DoD beneficiaries to participate in NCI sponsored clinical trials in cancer prevention in addition to cancer treatment under demonstration authority. On June 20, 2006, the DoD published a final rule to implement title 10, United States Code, section 1079(a)(13) which gives DoD the authority to cover NCI sponsored clinical trials as a TRICARE benefit. The cancer clinical trials demonstration project will be terminated on March 31, 2008, and DoD will implement the cancer clinical trial benefit on April 1, 2008.

PURPOSE:

The purpose of this interagency agreement is to continue the partnership and allow DoD beneficiaries to participate in NCI sponsored clinical trials in cancer prevention and cancer treatment as a benefit of the TRICARE program. The DoD shares public and scientific concern about disappointing cure rates under standard cancer management and has an interest and a responsibility to participate in the appropriate evaluation of improved approaches for DoD patients with and without cancer. Through this agreement, the DoD will have access to some of the most promising advances in cancer research through NCI sponsored clinical trials throughout the country by participating in the evaluation of emerging new protocols that have significant promise for the prevention and successful treatment of cancers.

SCOPE:

1. The DoD participation in this agreement includes only Phase II and Phase III clinical trials for cancer prevention or management of established disease. There are four non-mutually exclusive categories of NCI clinical trials sponsorship. They include trials reviewed and approved by the Cancer Therapy Evaluation Program or, as appropriate, the Division of Cancer Treatment, NCI Cooperative Group studies, studies that are conducted in clinical and comprehensive cancer centers under an NCI approved protocol review monitoring system, and NCI Grant studies.

2. All medical care and testing required to determine eligibility for an NCI sponsored clinical trial, including the evaluation for eligibility at the institution conducting the NCI sponsored study, will be provided or reimbursed by the DoD. Preauthorization is required, as described in Item 12, before initial evaluation.

3. All medical care required as a result of participation in approved clinical trials will be provided by MTFs or by civilian providers engaged in the NCI sponsored studies, who will be reimbursed by DoD following TRICARE reimbursement rules. This includes purchasing and administering all approved chemoprevention agents or chemotherapy agents (except for the investigational agent), cancer screening tests, treatment of complications of care, and diagnostic care. This also includes necessary follow-up care and testing that takes place after the period of treatment or protocol is completed.

4. All DoD MTFs providing oncology services will be allowed to apply for participation in NCI protocols for both adult and pediatric cancers according to the usual NCI Cooperative Group or other clinical trials participation review process.

5. Any TRICARE authorized provider providing oncology services will be allowed to apply for participation in NCI protocols in both adult and pediatric oncology studies according to the usual NCI Cooperative Group or other clinical trials participation review process.

6. The DoD shall not provide reimbursement for costs associated with any non-treatment research activities associated with participation in clinical trials. These include, but are not limited to: data collection activities, management and analysis of the data, salaries of the research nurses, and the cost of the investigational agents (if used in the protocol). These research costs will not be the responsibility of the patient participating in the clinical trials. The DoD shall not provide reimbursement for care rendered in the National Institutes of Health Clinical Center.

7. NCI will provide to MTFs and civilian providers an active information system through the Physician Data Query (PDQ). This system will provide quick access to information on NCI sponsored clinical trials open to patient accrual throughout the country. The system will identify clinical trials and participating investigators at the nearest or most appropriate medical facility.

8. No TRICARE reimbursement will be allowed for participation in clinical trials that are not sponsored or approved by NCI. TRICARE will reimburse any other NIH sponsored or approved cancer clinical trials approved in the future by the Assistant Secretary of Defense for Health Affairs. NCI sponsored clinical trials will be listed in the PDQ. In the event that a particular clinical protocol is not listed in the PDQ, NCI will provide status information to determine if the protocol has received NCI sponsorship, but has not yet been entered into the PDQ. NCI will assist in identification of eligible NCI sponsored clinical trials.

9. The NCI shall provide administrative support to coordinate all NCI activities related to this joint effort. DoD will provide a point-of-contact who will coordinate DoD activities under this agreement.

10. The DoD and the NCI will jointly develop and conduct programs to educate MTFs and civilian providers about this clinical trials initiative and the information systems that are available for referral.

11. The DoD and the NCI will jointly participate in education initiatives to inform the DoD eligible community of the opportunity to participate in NCI sponsored studies.

12. The DoD will require preauthorization of any patient participation in clinical trials that will be reimbursed by TRICARE through verification of the proposed trial in

PDQ. DoD will maintain the centralized toll-free telephone number to support this preauthorization requirement.

13. All TRICARE rules, regulations, and policies continue to apply to the care provided and any exceptions specific to this agreement shall be implemented in the regulation/policies implementing Title 10, United States Code, section 1079(a)(13). This includes, but is not limited to policies on referrals, authorized providers, and managed care requirements.

14. The cancer clinical trials demonstration project rules will continue to apply to DoD beneficiaries who began participation in cancer clinical trials demonstration before the effective date of this agreement. Such rules will continue to apply until the beneficiary is discharged from the clinical trial.

15. This agreement may be modified at the request of either party. The party desiring modification of the agreement shall provide, in writing, a 90 day advance notice to the other party indicating the intent to modify the agreement.

16. The effective date of this agreement is April 1, 2008.

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